

**REMARKS/COMMENTS**

**I. Introduction**

The present response to the final office action is being presented in response to the Notice of Abandonment issued on November 27, 2007 and to the final office action issued on April 30, 2007.

Applicant filed a Petition for Revival of an Application for Patent Abandoned Unintentionally Under 37 C.F.R. 1.137(b) along with a petition fee for a small entity of \$770.00, and a Terminal Disclaimer and disclaimer fee of \$65.00 disclaiming the required period of time on July 16, 2008. Applicant has filed, concurrently with this response, a Renewed Petition Under 37 C.F.R. 1.137(b).

**II. Amendments to the claims**

Applicant has amended the claims to properly indicate the status of the data and the Invention recite wherein the alpha FSH and beta FSH subunits do not comprise intervening polypeptide sequences. Support for this amendment can be found throughout the specification and specifically on page 4 of the specification in the first full paragraph.

**III. Rejections under 35 U.S.C. § 103**

The Examiner has rejected claims 1-32 and 34-35 under 35 U.S.C. § 103(a) as being unpatentable over Lustbader (US Patent No. 7,081,446) in view of Florkiewicz (US Patent No. 5,891,855) and further in view of Biome et al. (US Patent No. 6,238,890).

**A. The Claims**

Claim 33 has been amended to recite polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 27, wherein said polypeptide does not comprise a linker sequence.

**B. Applicant's arguments**

According to the Examiner, Lustbader encodes a synthetic chimeric FSH construct wherein the construct comprises a polypeptide segment between the alpha-FSH subunit and the beta-FSH subunit. Lustbader specifically discloses that the subunits are bound to each other via a half-life increasing moiety which is a polypeptide sequence covalently bound to each subunit. Nowhere in Lustbader is contemplated an alpha-FSH and beta-FSH chimeric construct that does not comprise an intervening polypeptide sequence. The Examiner further acknowledges that Lustbader fails to disclose SEQ ID NO: 27. In order to cure this acknowledged deficiency, the Examiner has cited Florwick for the disclosure of amino acids 1-116 of SEQ ID NO:27 (alpha-subunit) and Boime et al. for the disclosure of amino acids 117-227 of SEQ ID NO:27 (beta-subunit).

The Examiner explicitly stated that the claims as previously presented recited open language such that the polypeptide of the claim embraced intervening linker sequences. Consistent with the Examiner's concern, claim 33 has been amended to recite that no intervening polypeptide sequences can be present in the claimed invention.

It is fundamental to any *prima facie* obviousness rejection that each and every element of the claimed invention must be taught by the references either explicitly or implicitly. According

to MPEP 2103.03, when evaluating claims for obviousness under 35 U.S.C. 103, all the limitations of the claims must be considered and given weight. *Ex parte* Grasselli, 231 USPQ 393 (Bd. App. 1983) *aff'd* memo 738 F.2d 453 (Fed. Cir. 1984).

Neither Florkiewicz nor Boime et al. teach a chimeric alpha/beta FSH construct of SEQ ID NO:27 without intervening amino acid sequences. Since Lustbader also fails to teach that the chimeric constructs do not have intervening sequences, Lustbader fails to meet this limitation as well. Because, the disclosure of Lustbader specifically and exclusively discusses the half-life increasing moiety (i.e. intervening sequence) as a part of the chimeric polypeptide, it cannot be asserted that it even implicitly teaches such an element. In view of the foregoing, the cited prior art, taken as a whole, fails to teach each and every element of the claimed invention. Therefore, the invention would not have been obvious to one of skill in the art at the time the invention was made.

#### **IV. Formal Matters and Conclusion**

Applicants submit that the claims presently pending in the application are patentably distinct from the prior art of record and are in condition for allowance. The Examiner is respectfully requested to pass the above application to issue at the earliest possible time. Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary.

The commissioner is authorized to charge any fees as deemed necessary ("small entity" status) to Deposit Account No. 50-4364, from which the undersigned is authorized to draw.

Respectfully Submitted,

Dated: November 7, 2008

/Konstantina M. Katcheves/

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